

CLAIM AMENDMENTS

1. (Original) Multiparticulate formulation in form of microgranules or micro-tablets having dimensions ranging from 200 to 2000 micrometers, containing Lithium salts, characterized by the fact that said microgranules or micro-tablets have a modified release or that said microgranules or microtablets have partly a modified release and partly a conventional release, said formulation having a Lithium salt content of at least 500 mg/g and an in vitro dissolution profile that make it suitable for once-a-day administration.

A² 2. (Original) Formulation according to claim 1, realized with a Lithium salt dosage up to 1000 mg / dose expressed as Lithium Carbonate.

3. (Original) Formulation according to claim 1, wherein said Lithium salt content is at least of 900 mg/g.

4. (Cancelled)

5. (Currently Amended) Formulation according to claim 1, wherein said Lithium salt is ~~chosen~~ selected from the group ~~including~~ consisting of Lithium Carbonate, acetate, glutamate, thionate and sulphate.

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com. 6. (Currently Amended) Formulation according to claim 1, wherein the conventional release granules have no coating with agents modifying the dissolution speed, while the modified release granules have a coating with substances ~~chosen~~ selected from the group ~~including~~ consisting of polymers of acrylic and metacrylic acid, cellulose derivatives, stearic acid, paraffin, shellac, zein, or mixtures of the same in any proportion, optionally charged, ~~if necessary~~, with therapeutically acceptable plasticizers.

7. (Currently Amended) Formulation according to claim 6, wherein said polymers of

acrylic and metacrylic acid are ~~chosen~~ selected from the group ~~including~~ consisting of Eudragit L®, Eudragit RS® and Eudragit RL®. poly (methacrylic acid-co-methyl-methacrylate), 1:1, 135,000 MW, poly (methacrylic acid-co-ethyl acrylate), 1:1, 250,000 MW, poly (ethyl acrylate-co-methyl methacrylate-co-trimethyl amonioethyl methacrylate chloride), 1:2:0.1, 150,000 MW, and poly (ethyl acrylate-co-methyl methacrylate-co-trimethyl amonioethyl methacrylate chloride), 1:2:0.2, 150,000 MW.

8. (Currently Amended) Formulation according to claim 6, wherein said cellulose derivatives are ~~chosen~~ selected from the group ~~including~~ consisting of ethylcellulose, hydroxypropylmethylcellulose, hydroxypropylmethylcellulosephthalate, celluloseacetatephthalate.

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9. (Original) Formulation according to claim 6, including conventional release granules and modified release granules, in any proportion.

10. (Currently Amended) ~~Procedure for the preparation of A~~ process for preparing the formulation as defined in of claim 1, including the following ~~stages~~ steps:

a) ~~granulation of granulating~~ a Lithium salt in powder with a solution of a binder ~~chosen selected~~ from the group ~~including~~ consisting of polyvinylpyrrolidone, polyethyleneglycol, saccharose and gelatin;

b) sieving ~~of~~ the granules obtained in stage step a) ranging from 200 to 2000 micrometers ~~with the obtainment of a conventional to obtain a~~ release formulation;

c) coating of all or part of the granules obtained in stage step b) ~~with the obtainment of a to obtain the~~ modified release formulation.

11. (Currently Amended) ~~Procedure~~ The process according to claim 10, wherein said Lithium salt in powder has a granulometry lower than 100 micrometers.

12. (Currently Amended) ~~Procedure~~ The process according to claim 10, wherein said binder solution is a water solution or an organic solvent solution.

13. (Currently Amended) **Procedure** The process according to claim 10, wherein said organic solvent is ethanol.

14. (Currently Amended) **Procedure** The process according to claim 10, wherein said binder solution has a concentration ranging from 3 to 20%.

15. (Currently Amended) **Procedure** The process according to claim 10, wherein the quantity of the binder utilized in the granulation ranges from ~~0.5%~~ 0.5% to 15% compared to the Lithium salt.

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16. (Currently Amended) **Procedure** The process according to claim 10, wherein ~~said coating of the granules is realized~~ are coated with substances ~~chosen~~ selected from the group including consisting of polymers of acrylic and metacrylic acid, cellulose derivatives, stearic acid, paraffin, shellac, zein, or mixtures of the same in any proportion, optionally charged, if ~~necessary~~, with therapeutically acceptable plasticizers.

17. (Currently Amended) **Procedure** The process according to claim 16, wherein said polymers of acrylic and metacrylic acid are ~~chosen~~ selected from the group consisting of ~~including Eudragit L®, Eudragit RS® and Eudragit RL®.~~ poly (methacrylic acid-co-methyl methacrylate), 1:1, 135,000 mw, poly (methacrylic acid-co-ethyl acrylate), 1:1, 250,000 mw, poly (ethyl acrylate-co-methyl methacrylate-co-trimethyl amonioethyl methacrylate chloride), 1:2:9.1, 150,000 mw, and poly (ethyl acrylate-co-methyl methacrylate-co-trimethyl amonioethyl methacrylate chloride), 1:2:0.2, 150,000 mw. NO

18. (Currently Amended) **Procedure** The process according to claim 16, wherein said cellulose derivatives are ~~chosen~~ selected from the group including consisting of ethylcellulose, hydroxypropylmethylcellulose, hydroxypropylmethylcellulosephthalate, celluloseacetatephthalate.

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19. (New) Formulation according to claim 1 wherein the formulation has a dissolution

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profile where from 5-25% of the Lithium salt is dissolved in one hour, 20-45% is dissolved in four hours, 40-65% is dissolved in eight hours, 50-80% is dissolved in twelve hours; and 60-90% is dissolved in twenty four hours.
